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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,988	03/16/2001	Gerhard Scheuch		7304

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EXAMINER

DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,988	SCHEUCH ET AL.	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6, 8-11, 15-18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6, 8-11, 15-18 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
- 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention in claim 10 by the use of "adjusting means for adjusting...". Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542.

Appropriate correction is required.

Claim Objections

Claims 3-6 and 8-11 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6,8-11,15-18 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The means for adjusting and the adjustment mechanism claimed in the above claims has not been disclosed in such a way that one skilled in the art would have been able to make and use the device. It is unclear what structure would be capable of performing the claimed functions and exactly how it would interact or interconnect with the other explicitly claimed elements of the invention to arrive at the specified functions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6,8-11,15-18 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

One skilled in the art would not be able to identify the structure which makes up the claimed adjusting means or adjustment mechanism, thus making the scope of the claim unclear and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3,4,8,10,11,15,18,21,22 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman, et al.-5813397.

Goodman discloses a system of a ventilator which provides doses of an aerosol according to a patient specific protocol or regimen. Either a programmable microprocessor or a canister with a readable bar label has inputted therein patient and aerosol parameters (e.g. particle size distribution, pulse length and duration) into its memory. This memory is read and used to alter or adjust the operating parameters of the ventilator and aerosol device to provide the proper regimen. The device has the capability to detect changes in the patient's pulmonary functions or flow patterns including flow rate and tidal volumes and adjust these parameters. The inputted parameters can be requested by the microprocessor and obtained through a conventional external communications port. See col. 21 lines 30-42; col. 31 line 15- col. 32 line 7; col. 34 lines 30-46; col. 35 lines 1-2 and 63-65. Additionally see abstract lines 14-21; col. 5 lines 8-24; col. 6 lines 1-33; col. 8 lines 28-47; col. 12 lines 47-53; col. 15

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lines 37-55; col. 16 lines 11-27; col. 21 lines 43-52; col. 31 lines 3-14; lines 30-40,51-62;
col. 31 line 67-col. 32 line 7; col. 34 lines 30-34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5,6,9,16,17,23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, et al.-'397 in view of Wallace, et al.-6024089.

Goodman discloses the invention as claimed with the exception of the specific inputting means.

Wallace discloses the use of manually inputting means to input patient or ventilator parameters into the ventilator. It would have been obvious to have provided manual inputs for the ventilator so that it could be used if necessary even if the memory or labels were not present. To have used a modem connected to the disclosed conventional external communications port of Goodman, would have been obvious as modems were well-known at the time of the invention to be communication devices which allowed for remote data communication.

Response to Arguments

Applicant's arguments filed 08-30-2005 have been fully considered but they are not persuasive.

The examiner has pointed out the objectionable language in claim 10, namely the "means for" clause.

The last response did not offer any details as to exactly what the structure is that makes up the "adjusting means". Simply stating that the means is a valve is entirely insufficient. Exactly what type of valve is it and how is it structurally connected to the rest of the device to allow it to control the device? Since the claim invokes 112 6th, the applicant is required to specifically point out what structure makes up the claimed means. Providing possible means which one skilled in the art would recognize is

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unsatisfactory. The examiner needs to know what the applicant's means is in order to determine whether the prior art reads on the structure or discloses structure sufficiently analogous or equivalent so as to read on the claimed means. The art rejections are given in light of the examiner's understanding of the claimed device in an extremely broad context... that is the examiner contends that given the noted indefiniteness with regards to the structure making up the claimed means, the examiner contends that anything which performs the claimed function reads on the claimed means limitation.

Even though claim 25 does not claim the means, clearly the adjusting steps require the adjusting means and therefore have been included in the rejections.

Goodman clearly states that the device is intended to be flexible enough to use with a specific patient by reading information concerning operating parameters (at least aerosol parameters and most probably patient parameters) from a local or external memory source for customizing use by a specific patient. See col. 31 lines 3-14. The device can be remotely re-programmed or can rely on information on a label to change the operating parameters of the device. The code on the label causes the device to change its operating parameters. It is clear that the device is given information regarding both patient parameters and aerosol parameters, stored in memory either in a library, a microprocessor or on a label and upon reading the information, changes the operation of the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

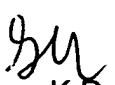
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Glenn K Dawson
Primary Examiner
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Gkd
02 November 2005